

10/528957**DT01 Rec'd PCT/PT 22 MAR 2005****In the Claims**

Please amend the claims presented during the international phase as follows.

Applicant presents a full set of claims showing markups of the claims with insertions and deletions indicated by underlining and strikethrough text, respectively.

1. (Original) A method of obtaining substantially pure cannabidiol (CBD) from plant material, which has a purity of greater than 95% as determined by area normalisation of an HPLC profile, which method comprises obtaining a cannabidiol-containing extract of the plant material, dissolving the extract in a solvent to form a solution, removing insoluble material from this solution and evaporating the solvent from the solution to obtain substantially pure cannabidiol, wherein the solvent is a C5-C12 straight chain or branched alkane or a carbonate ester of a C1-C12 alcohol.
2. (Original) A method according to claim 1 wherein the substantially pure preparation of cannabidiol (CBD) has a chromatographic purity of 98% or greater, preferably 99% or greater, and most preferably 99.5% or greater by area normalisation of an HPLC profile.
3. (Original) A method according to claim 2 wherein the substantially pure preparation of cannabidiol has a melting point in the range of from 64 to 66°C.
4. (Currently amended) A method according to claim 2 ~~or claim 3~~ wherein the substantially pure preparation of cannabidiol comprises less than 1%, preferably less than 0.8%, more preferably less than 0.6%, more preferably less than 0.4%, more preferably less than 0.2% and most preferably less than 0.1% Δ^9 THC.
5. (Currently amended) A method according to claim 1 ~~any one of claims 1 to 4~~ wherein the insoluble material is removed by filtration.
6. (Original) A method according to claim 1 wherein the solvent is pentane, hexane or propyl carbonate.
7. (Original) A method according to claim 6 wherein the solvent is pentane.

8. (Currently amended) A method according to ~~any one of the preceding claims~~ claim 1 wherein the cannabidiol-containing extract of the plant material is a botanical drug substance (BDS) derived from the plant material.
9. (Original) A method according to claim 8 wherein the botanical drug substance is prepared by a process comprising solvent extraction of the plant material.
10. (Original) A method according to claim 9 wherein the botanical drug substance is prepared by extraction with carbon dioxide, ethanol, methanol or hexane.
11. (Original) A method according to claim 10 wherein the botanical drug substance is prepared by a process comprising extraction with carbon dioxide (CO₂), followed by a secondary extraction step to remove a proportion of the non-target materials.
12. (Original) A method according to claim 11 wherein the secondary extraction step is ethanolic precipitation.
13. (Original) A method according to claim 11 which further includes a charcoal clean-up step.
14. (Original) A method according to claim 13 wherein the botanical drug substance is prepared by a process comprising:
- i) decarboxylation of the plant material,
 - ii) extraction with liquid CO₂, to produce a crude botanical drug substance,
 - iii) precipitation with C1-C5 alcohol to reduce the proportion of non-target materials,
 - iv) removal of the precipitate,
 - v) treatment of the resulting solution with activated charcoal, and
 - vi) removal of C1-C5 alcohol and water, thereby producing a final botanical drug substance.
15. (Currently amended) A method of obtaining substantially pure cannabidiol (CBD) from plant material comprising:
- i) decarboxylation of the plant material,
 - ii) extraction with liquid CO₂, to produce a crude botanical drug substance,

iii) precipitation with ethanol to reduce the proportion of non-target materials,
iv) filtration to remove the precipitate,
v) treatment of the resulting solution with activated charcoal, ~~and~~
vi) removal of ethanol and water from the solution to produce a CBD-enriched extract,
vii) re-dissolving the CBD-enriched extract in a C5-C12 straight chain or branched
alkane or a carbonate ester of a C1-C12 alcohol, and
vi) removal of solvent from the solution of step vii) to obtain substantially pure CBD.

16. (Original) A method according to claim 15 wherein the solvent of step v) is pentane.

17. (Currently amended) A method according to ~~any one of claims 1 to 16~~ claim 1
wherein the substantially pure cannabidiol is obtained in crystalline form.

18. (Original) A substantially pure preparation of cannabidiol (CBD) prepared from plant material using the method of claim 1, having a chromatographic purity of 98% or greater, preferably 99% or greater, and most preferably 99.5% or greater by area normalisation of an HPLC profile.

19. (Original) A substantially pure preparation of cannabidiol according to claim 18 which is a white crystalline solid at room temperature.

20. (Original) A substantially pure preparation of cannabidiol according to claim 19 which has a melting point in the range of from 64 to 66°C.

21. (Currently amended) A substantially pure preparation of cannabidiol according to ~~any one of claims 18 to 20~~ claim 18 which comprises less than 1%, preferably less than 0.8%, more preferably less than 0.6%, more preferably less than 0.4%, more preferably less than 0.2% and most preferably less than 0.1% Δ^9 tetrahydrocannabinol (THC).

22. (Currently amended) A substantially pure preparation of cannabidiol according to ~~any one of claims 18 to 21~~ claim 18 which comprises less than 1%, preferably less than 0.8%, more preferably less than 0.6%, more preferably less than 0.4%, more preferably less than 0.2% and most preferably less than 0.1% cannabinol (CBN).

23. (Currently amended) A substantially pure preparation of cannabidiol according to ~~any one of claims 18 to 22~~ claim 18 which is obtained from cannabis plant material using a method comprising:

- i) decarboxylation of the plant material,
- ii) extraction with liquid CO₂, to produce a crude botanical drug substance,
- iii) precipitation with ethanol to reduce the proportion of non-target materials,
- iv) filtration to remove the precipitate,
- v) treatment of the resulting solution with activated charcoal,
- vi) removal of ethanol and water from the solution to produce a CBD-enriched extract,
- v) re-dissolving the CBD-enriched extract in pentane, and
- vi) removal of pentane from the solution of step v) to obtain substantially pure CBD.

24. (Canceled)

25. (New) A substantially pure preparation of cannabidiol having an HPLC profile with a CBD retention time of 5.1-5.8 minutes.